

*Innovating  
antibodies,  
improving lives*



## Senior Medical Writer

*Genmab is an international biotechnology company specializing in the creation and development of differentiated human antibody therapeutics for the treatment of cancer.*

Genmab is looking for a highly motivated, independent and talented Medical Writer with a minimum of 5 years' experience from the Pharmaceutical Industry. As Senior Medical Writer you will be responsible for driving, developing and writing clinical documents to support operational, medical and regulatory activities across Genmab projects. As Senior Medical Writer you will be responsible for ensuring implementation of scientifically robust messages and arguments are developed and conveyed consistency across documents. We expect you have an academic degree in life sciences. Ideally, you have a broad background which has given you a solid knowledge on clinical drug development and regulatory requirements.

**Are you the Senior Medical Writer with flair for words and a passion for accuracy? The successful candidate will have strong analytical skills, high quality standards and is committed to meet deadlines. In addition, it is essential that you are well-organized, pro-active, and flexible, and have the ability to work on multiple tasks.**

**We offer a position where you will be involved in project strategic as well as trial related activities, and will have ample opportunities, responsibilities, and influence on defining your own work. You will also be involved in developing of processes and tools to support further development of the department.**

### **Job content:**

This is a newly established position and you will be reporting to the Senior Director, Clinical Operations. As Senior Medical Writer, you will work closely with the clinical management team. Your key responsibilities will be:

- Draft and edit documents used during clinical trial conduct and reporting including clinical trial protocol, investigators brochures and clinical study reports.
- Drive trial team participation in the preparation of such documents, including calling/scheduling/running meetings, developing and managing timelines, document review and decisions.
- Provide peer review and editing support for other clinical / regulatory documents, such as DSUR and various clinical documents as needed.
- Adhere to guidelines, SOPs and practices and technical and industry standards during all aspects of work.
- Support developing and reviewing standard processes and templates.
- Work effectively in cross functional working groups.

### **Professional profile:**

- At least 5 years of medical or scientific writing experience as primary job responsibility including at least 3 years as a clinical or regulatory medical writer in the pharmaceutical industry, preferably within oncology.
- Experience in scientific/technical writing preferable evidence e.g. AMWA/EMWA certification or similar.
- Proficiency in the use and understanding of computer software e.g. word processing, graphics, reference manager, document management.

- Familiarity with all phases of drug development processes (discovery to market), clinical study protocol design, CTA/IND submissions, investigator brochure and potentially plans required for the conduct of clinical studies, and clinical study data collection and results reporting.
- Knowledge of routine document content preparation, including the use of style guides, medical dictionaries, and regulatory guidance documents and templates.
- Experience writing protocols, investigator's brochures and clinical study reports.
- General understanding/knowledge of regulatory requirements and drug development processes, regulatory requirements and guidelines associated with regulatory documents (e.g., protocols, investigator brochures, and clinical study reports).
- Ability to interpret and summarize tabular and graphical data presentations.
- Experience writing briefing packages to FDA and EMA.
- Experience working with Adobe.
- Fluency in English with good verbal and written communication skills is a given.
- Native English speaker, desirable but not a requirement.

#### **Personal profile:**

- You are capable of working on multiple tasks and shifting priorities, and leading cross-functional teams under strict timelines.
- You are motivated and detail orientated.
- You have ability to work across all trial phases and priorities own tasks.
- You are a dedicated team player and a great communicator with excellent social skills.
- You are proactive and open minded.
- You have a quality mind-set and are able to prioritise your work in a fast paced and changing environment.
- You are result- and goal-oriented and committed to contributing to the overall success of Genmab.

#### **A promising future and a short chain of command**

Genmab is a small biotech company with a short chain of command. You will have opportunity to influence your own work as well as your personal and professional development. You will also have flexible working hours and conditions.

#### **And a dynamic and innovative environment**

Our commitment to bringing new medicines to the market to improve patients' lives is a strong motivation for employees at Genmab. Our aim is to foster a culture of excellence and innovation where employees are focused on clear priorities and are passionate about innovation. We work cross-functionally and internationally as one team to gain the most from all competencies.

Genmab employees work with determination and with respect for each other to achieve our tasks and common goals. We give individuals and team the autonomy to drive development of innovative products and solutions, knowing that integrity is a core value throughout our company.

#### **How to apply:**

Please contact Hanne Beirholm at +45 29 44 00 80. Resumes to be sent to Beirholm Search at [job@beirholmsearch.dk](mailto:job@beirholmsearch.dk)

Interviews will be conducted on an ongoing basis, so please do not hesitate to apply.